

Persona Nederland

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25943

Source

NTR

Health condition

Knee osteoarthritis, total knee prosthesis, total knee arthroplasty, knie artrose, totale knieprothese, totale knie arthroplastiek

Sponsors and support

Primary sponsor: Department of Orthopaedics, Reinier de Graaf Groep

Source(s) of monetary or material Support: Zimmer Biomet

Intervention

Outcome measures

Primary outcome

Implant survivorship based on removal of study device

Secondary outcome

Safety, based on incidence and frequency of adverse events

Clinical performance measured by overall pain and function, quality of life data, radiographic parameters and survivorship. Outcome measures are: Knee Society Objective Knee Score, KOOS score, EQ-5D and Oxford Knee Score

Study description

Background summary

Rationale

TKA has demonstrated effectiveness with substantive and sustained improvement in quality of life for individuals with moderate to severe osteoarthritis, however, functional performance in patients 1 year after TKA remains lower than for healthy adults, with reports of an 18% slower walking speed, 51% slower stair-climbing speed, and deficits of nearly 40% in quadriceps strength. Additionally, certain limitations in knee design systems require surgeons to accept compromises which can result in surgical inefficiencies and challenges in seizing desired outcomes. Patient expectations and an ever emerging population with active lifestyle also add a new requirement and need for innovative designs that bring advantages over traditional implants. Personalized implants with critical features of natural movement, contoured shape, and unique anatomic and physiologic composition can address these requirements.

This study will evaluate the commercially available Zimmer Persona knee implant used in primary total knee arthroplasty, a more personalized knee implant.

Objective

The primary objective of this study is to obtain implant survivorship and clinical outcomes data for commercially available Persona knee implants used in primary total knee arthroplasty.

Study design

A prospective multicenter, non-controlled study of commercially available Zimmer Persona knee implants will be enrolled. Patients will be evaluated preoperatively, during hospital stay and at 6 weeks, 1 year, 2,3,4, and 5 years post-operative.

Study population

The study population will consist of 200 patients who qualify for primary total knee arthroplasty and who meet the inclusion/exclusion criteria for study participation.

Intervention

The Zimmer Persona knee implant

Main study parameters/endpoints

1. Implant survivorship based on removal of a study device.
2. Safety based on incidence and frequency of adverse events.
3. Clinical performance measured by overall pain and function, quality of life data, radiographic parameters and survivorship.

Study design

Preoperative, during hospital stay, 6 weeks, 1 year, 2 years, 3 years, 4 years, 5 years

Intervention

total knee arthroplasty with the Zimmer Persona knee implant

Contacts

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Eligibility criteria

Inclusion criteria

- Patiënt is 18-75 years of age
- Patient qualifies for a primary total knee arthroplasty based on physical exam and medical history, including diagnosis of severe knee pain and disability due to at least one of the following: a: Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis. b: Collagen disorders and/or avascular necrosis of the femoral condyle. c: Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy. d: Moderate valgus, varus, or flexion deformities. e: The salvage of previously failed surgical attempts that did not include partial or total knee arthroplasty of the ipsilateral knee.
- Patient is willing and able to complete scheduled study procedures and follow-up evaluations
- Independent of study participation, patient is a candidate for commercially available Zimmer Persona knee implants implanted in accordance with product labeling

Exclusion criteria

- Patient is currently participating in any other surgical intervention studies or pain management studies
- Previous history of infection in the affected joint and/or other local/systemic infection that may affect the prosthetic joint
- Insufficient bone stock on femoral or tibial surfaces
- Skeletal immaturity
- Neuropathic arthropathy
- Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb
- Stable, painless arthrodesis in a satisfactory functional position
- Severe instability secondary to the absence of collateral ligament integrity
- Rheumatoid arthritis accompanied by an ulcer of the skin or a history of recurrent breakdown of the skin
- Patient has a known or suspected sensitivity or allergy to one or more of the implant

materials

- Patient is pregnant or considered a member of a protected population (e.g., prisoner, mentally incompetent, etc.)
- Patient has previously received partial or total knee arthroplasty for the ipsilateral knee.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2014
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	13-07-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6391
NTR-old	NTR6566
Other	14-071 : METC ZWH

Study results